

§ 1.730

37 CFR Ch. I (7–1–00 Edition)

(h) No other patent term has been extended for the same regulatory review period for the product.

[52 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989]

§ 1.730 Applicant for extension of patent term.

Any application for extension of a patent term must be submitted by the owner of record of the patent or its agent and must comply with the requirements of § 1.740.

§ 1.740 Application for extension of patent term.

(a) An application for extension of patent term must be made in writing to the Commissioner of Patents and Trademarks. A formal application for the extension of patent term shall include:

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics;

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred;

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred;

(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted;

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration;

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings;

(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent;

(9) A statement that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product or method of using or manufacturing the approved product;

(10) A statement, beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product, the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number and the date on which the NDA was approved or the Product License issued;

(ii) For a patent claiming a new animal drug, the date a major health or environmental effects test on the drug was initiated and any available substantiation of the date or the date of an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act became effective for such animal drug; the date on which a new animal drug application (NADA) was initially submitted and the NADA number; and the date on which the NADA was approved;

(iii) For a patent claiming a veterinary biological product, the date the authority to prepare an experimental biological product under the Virus-

Serum-Toxin Act became effective; the date an application for a license was submitted under the Virus-Serum-Toxin Act; and the date the license issued;

(iv) For a patent claiming a food or color additive, the date a major health or environmental effects test on the additive was initiated and any available substantiation of that date; the date on which a petition for product approval under the Federal Food, Drug, and Cosmetic Act was initially submitted and the petition number; and the date on which the FDA published the FEDERAL REGISTER notice listing the additive for use;

(v) For a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which the application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug, and Cosmetic Act was initially submitted and the number of the application or protocol; and the date on which the application was approved or the protocol declared to be completed.

(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined;

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (see § 1.765);

(14) The prescribed fee for receiving and acting upon the application for extension (see § 1.20(j)).

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed;

(16) A duplicate of the application papers, certified as such; and

(17) An oath or declaration as set forth in paragraph (b) of this section.

(b) Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:

(1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.

(2) Has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) Believes the patent is subject to extension pursuant to § 1.710;

(4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

(c) If any application for extension of patent term submitted pursuant to this section is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to § 1.181, § 1.182 or § 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR 1.136.

[54 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989; 56 FR 65155, Dec. 13, 1991]